IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYVLANIA

JILL SIKKELEE, Individually and as Personal Representative of the ESTATE OF DAVID SIKKELEE, Deceased,	:	Case No. 4:07-cv-00886-MWB
	:	The Honorable Matthew Brann
Plaintiff	:	
v.	:	
	:	Complaint Filed:
PRECISION AIRMOTIVE CORPORATION, et al.,	:	May 16, 2007
Defendants	:	

PLAINTIFF'S BRIEF IN OPPOSITION TO DEFENDANT AVCO CORP.'S ("LYCOMING'S") MOTION FOR SUMMARY JUDGMENT ON CONFLICT PREEMPTION GROUNDS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Regulations

Other Authorities

INTRODUCTION

The Third Circuit's opinion recognized that a type certificate could give rise to conflict preemption because "there may be cases where a manufacturer's compliance with both the type certificate and a state law standard of care is a physical impossibility." *Sikkelee v. Precision Airmotive Corp.*, 822 F.3d 680, 704 (3d Cir. 2016) (quotation marks omitted). Impossibility, however, "is a demanding defense." *Wyeth v. Levine*, 555 U.S. 555, 573 (2009). To prove it here, Lycoming must show two things. First, the challenged "aspect of an aircraft's design" must have been "expressly approved by the FAA as shown on the type certificate" or an incorporated document. *Sikkelee*, 822 F.3d at 704. Second, the type certificate holder must not be able to modify that aspect of the design. *See id.* at 703-04 & n.21. This second inquiry is "a matter of fact." *Wyeth*, 555 U.S. at 572. To carry its burden, Lycoming must present "clear evidence" that the FAA would not have approved a change, had Lycoming sought to implement one. *Id*. at 571.

Lycoming's summary judgment motion (ECF No. 532) therefore is most notable for what it does not say. It does not argue that its type certificate for the O-320 engine expressly approved the use of lock tab washers to secure the carburetor throttle body to the float bowl. Nor does Lycoming argue that federal law prohibits it from complying with Pennsylvania law—whether by altering the design of the O-320 engine to make it safe, by issuing accurate warnings, or by reporting the

known defect to the FAA. Its statement of facts (ECF No. 533) is likewise silent on these points. Thus, Lycoming does not assert any conflict between its obligations under federal and state law that would implicate the Supremacy Clause.

Instead, Lycoming argues that the federal regulations referring to parts manufacturer approval (PMA) prohibited a different entity, Kelly Aerospace, from modifying Lycoming's defective fuel system design because the FAA approved each replacement part, including the lock tab washers, screws, and gasket materials, and did not approve an alternative design. On that basis, Lycoming argues that federal and state law conflict, and so state law must yield.

This motion rests on a non-sequitur. Kelly's PMA approves the replacement parts that Kelly produces and sells for use in the MA-4SPA carburetor. But it does not reach back to approve any part of Lycoming's design, and therefore does not satisfy the Third Circuit's requirement that an express approval of the challenged design feature be incorporated into the type certificate. Moreover, Kelly's obligations as a parts manufacturer do not encumber Lycoming—which, as the type certificate holder, has a different set of obligations as well as substantial freedom to modify its designs—and therefore do not make it impossible for Lycoming to comply with its own duties under state law. Lycoming certainly has not presented "clear evidence" to the contrary. At a minimum, disputed questions of fact preclude summary judgment.

STATEMENT

The facts have not changed since the last time this Court denied summary judgment. Lycoming holds the type certificate for the O-320 engine. As such, Lycoming alone has the power to choose which parts to use on the engine, and how they are configured. ECF No. 546 ¶¶24, 26. Lycoming specified that the MA-4SPA carburetor must be used in the O-320-D2C variant. *Id*. ¶25. In 1965, Lycoming adopted an engineering change order further requiring the throttle body to be attached to the carburetor float bowl using four screws secured with lock tab washers. *Id*. ¶28. The design cannot be changed without Lycoming's approval. *Id*. ¶26.

This design is defective because the throttle body to bowl screws frequently loosen due to engine vibration in O-320-D2C engines installed on Cessna 172 series aircraft. When these screws loosen, the engine can lose power. *Id*. ¶34. The defect has been well-documented by the FAA, by carburetor manufacturer Precision Airmotive, and by Lycoming itself, and it has persisted for decades. *Id*. ¶¶27, 29-31, 34. It also caused the crash that killed Jill Sikkelee's husband David, giving rise to this litigation. *Id*. ¶43. The complaint alleges strict liability and negligence, on theories of defective design, failure to warn, and failure to notify the FAA of a known defect. ECF No. 205.

Lycoming has the power to change the design. It can implement minor changes without the FAA's preapproval, 14 C.F.R. § 21.95, and major ones after agency approval, which the FAA regularly grants to Lycoming, *id*. § 21.97. Lycoming's O-320 type certificate is illustrative: it has been revised twenty-two times to authorize sixty variants of the engine. ECF No. 234-9, at 4 (showing application and approval dates). Lycoming has also certified thirty-two variants of a fuel-injected version of the O-320. *See* Type Certificate Data Sheet No. 1E12, at 2-3, *available at* http://tinyurl.com/nwcdmpa (same). The vast majority of these ninety-two engine variants were approved in less than a month—some in less than a week.

Alternatives to the current design were and are feasible. Indeed, Lycoming already sells O-320 engines that do not use the MA-4SPA carburetor. Two certified variants (D1D and B2D) use the HA-6 carburetor, which does not exhibit the defect. ECF No. 546 ¶25. The thirty-two fuel-injected alternatives also avoid this defect.

Aside from those alternatives, Lycoming could use safety wire—a more effective method with only minor differences from the current design. In fact, the FAA had previously required MA-4SPA carburetors to "[s]afety all bowl cover screws . . . by the use of safety wire." FAA, Airworthiness Directive (AD) 64-27-2,

29 Fed. Reg. 16,318 (Dec. 4, 1964).[1] Lycoming shifted away from that design using an Engineering Change Order, a method that does not require FAA preapproval. ECF No. 546 ¶28.

Kelly Aerospace, Inc. is the holder of a PMA. This means that Kelly may produce certain replacement "articles" (parts) for type certificated products, including carburetor parts for the MA-4SPA carburetor in the Lycoming O-320-D2C engine. ECF No. 546 ¶35. To obtain a PMA for a particular article, Kelly was required to submit "[t]est reports and computations" that are "applicable to the product [*e.g.*, engine] on which the article is to be installed," showing that the proposed article meets applicable airworthiness requirements—or else show that the design of the article is "identical to the design of an article that is covered under a type certificate." 14 C.F.R. § 21.303(a)(4).

A common way that PMA applicants show that their products meet applicable airworthiness requirements is the "comparative analysis approach." FAA, Parts Manufacturer Approval Procedures, Order 8110.42D, at 2-8 (2014). This involves comparing "a PMA article to a [type certificate] holder's or licensee's article to identify design differences and their effects on associated compliance with regulations." *Id*.

[1] As explained in our Statement of Facts, this AD was amended several times and eventually revoked. ECF No. 546 ¶27 & n.2. Although the carburetor in this case was not produced in violation of an AD, no AD ever expressly approved of the lock tab washer design for the MA-4SPA carburetor either.

Thus, to obtain approval for its replacement articles, Kelly tested an OEM carburetor for a period of time (*e.g.*, 150 hours), and then tested a carburetor that contained Kelly parts for the same period of time. It then prepared a report documenting that its parts performed just as well or better than the OEM parts. ECF No. 546 ¶36. Because that test data showed that Kelly's carburetor parts conformed in every material sense to Lycoming's engine design, including the MA-4SPA carburetor, Kelly was permitted to sell parts for use in that design. ECF No. 533, ¶11.

In 2004, Kelly overhauled an OEM MA-4SPA carburetor for installation on the Lycoming O-320-D2C engine in this case, using some of its own parts in lieu of some of the OEM parts. ECF No. 546 ¶38. But the carburetor remained an MA-4SPA carburetor: its overall design was the one chosen by Lycoming, and Kelly complied with the OEM manuals and with Lycoming's Service Bulletin SB 366, which is defective because it provides incorrect and dangerous instructions for addressing the problem of loose throttle body to bowl screws. *Id*. ¶¶38-41.

The Lycoming engine was used in a Cessna 172 series aircraft. The screws between the throttle body and the bowl of the carburetor loosened during flight, causing the loss of engine power and crash that killed David Sikkelee. *Id*. ¶43. Lycoming has long known of this defect, and of its propensity to cause crashes. *Id*. ¶34.

ARGUMENT

I. Kelly's Obligations As A PMA Holder Do Not Make It Impossible For Lycoming To Comply With Pennsylvania Law.

Lycoming asks the Court to "assum[e] for purposes of this motion only that Lycoming somehow could be held liable for alleged design defects in Kelly's replacement carburetor." ECF. No. 534, at 2-3. Under that assumption, the necessary implication is that Pennsylvania law imposes a duty on Lycoming to do something different than it did, *e.g.*, to design the engine free of defects, issue different warnings, and/or report the flaws in its design to the FAA. The conflict preemption question is whether Lycoming has shown that any federal law prohibits it from fulfilling those duties.

The clear answer is no. Lycoming does not even argue that federal law prevents *it* from doing anything. Instead, Lycoming's motion is all about the constraints federal law places on *Kelly*. *See, e.g.*, ECF No. 534, at 4 (stating the question as whether summary judgment is appropriate "because federal law prohibits Kelly from making the design changes to the carburetor's attachment mechanism that plaintiff asserts are required by Pennsylvania law"). While we could see how Lycoming's argument (if meritorious) might give rise to a conflict preemption defense *for Kelly*, Lycoming never explains how federal constraints on Kelly encumber Lycoming. They do not because any restrictions on Kelly as a parts manufacturer simply do not apply to Lycoming as the type certificate holder. In

making the contrary argument, Lycoming appears to suggest that when a third party's federal and state obligations clash, a defendant is entitled to summary judgment on grounds of impossibility preemption. But it cites no authority for that proposition, and we are aware of none.

In fact, type certificate holders and PMA holders are regulated by different subparts of the Federal Aviation Regulations, and thus have different responsibilities. *See* 14 C.F.R. Subpart B (type certificates), Subpart K (PMA). The type certificate holder is responsible for the original design of aircraft, engines, and propellers (each, in terms of the regulations, a "product"). 14 C.F.R. § 21.1(b)(6). PMA holders manufacture "articles," *i.e.*, the component parts of products. *Id*. § 21.1(b)(2). Thus, a type certificate holder like Lycoming designs an engine, specifies which carburetor to put on it, and further specifies how that carburetor should be designed. ECF No. 546 ¶24. No other company can modify that design. *Id*. ¶26. A PMA holder designs components of that engine—in Kelly's case, a smattering of parts for the carburetor. The PMA holder proves the suitability of its articles principally by comparing them to the type certificate holder's, meaning that any differences between a PMA article and an OEM part will typically be minor. Moreover, because the PMA holder is trying to sell articles for installation on the type certificated product, it has every incentive to follow the type certificate holder's design as closely as possible. *Id*. ¶¶36-37, 39-41. Here, Lycoming admits

that Kelly's parts had the fit, form, and function called for by Lycoming's engine design. ECF No. 533 ¶11.

That is why courts have explained that type certificate holders like Lycoming "sit at the top of the aviation food chain with respect to all components comprising the type certificated engine," such that they may "be liable for design defects in replacement parts and/or the aircraft systems within which such components function." *Pridgen v. Parker Hannifin, Corp.*, 916 A.2d 619, 623 (Pa. 2007). Similarly, with respect to the carburetor in this case, the FAA has explained that "Marvel Schebler carburetors are a part of the engine type design and are not approved separately," so that the "type certificate holder is responsible for the type design" and also for "[s]ervice problems which may be design related." ECF No. 234-13, at 3; *see also* ECF No. 299, at 8. And Lycoming's co-defendant Precision Airmotive, the PMA carburetor manufacturer, has likewise admonished that Lycoming, as the "type certificate holder," it should evaluate "the pros and cons of a different attachment system" for MA-4SPA carburetors in Cessna 172 aircraft. ECF No. 234-14, at 3-4.

Because of the different roles that type certificate holders and PMA holders occupy, and because of the different regulations that apply to them, any regulatory restriction preventing Kelly from modifying its PMA articles simply has no bearing on Lycoming's ability to comply with its various duties. For example,

Lycoming plainly had the authority—and the obligation—to issue appropriate warnings to users (under state law) and to report known defects in its design to the FAA (under 14 C.F.R § 21.3). None of the PMA regulations interfere with that, let alone make it impossible.

Even with respect to Lycoming's design, the PMA regulations pose no bar to complying with state law. As an initial matter, Lycoming already has certifications in place for two variants of the O-320 that do not use the defective MA-4SPA carburetor design, as well as 32 variants of a fuel-injected version of the engine. ECF No. 546 ¶¶4, 25. Thus, even without any design changes, Lycoming's existing type certificates allow it to sell O-320 engines that comply with state law. That fact alone defeats any claim of impossibility.

Even limiting the analysis to the O-320-D2C, type certificate holders can make "minor changes" to a design without the FAA's prior approval. *See* FAA, Designated Engineering Representative (DER) Handbook, Order 8110.37E, at 12, 24 (2011) (explaining that the manufacturer decides whether a change is minor—subject to FAA disapproval—and the DER can make minor changes "without prior authorization" by the certification authority). That power is a very close analogue to a brand-name drug manufacturer's ability to alter its drug labels under the "Changes Being Effected" regulation—a fact that defeated impossibility preemption in *Wyeth*. 555 U.S. at 568; *see also id.* at 571 (noting that the FDA was

free to subsequently reject the label change, but deeming that fact irrelevant to the impossibility analysis absent "clear evidence" that the FDA actually would have done so).

In this case, Lycoming has not presented any evidence that it even attempted to use its minor-change authority to specify a different gasket material or the use of safety wire in the O-320-D2C—let alone any evidence that the FAA either rejected or would have rejected the change. ECF No. 546 ¶32. Indeed, that is essentially how the change from safety wire to lock tab washers was processed in 1965: Lycoming simply used an engineering change order—even though at the time there was a contrary airworthiness directive in place. *Id.* ¶28. Lycoming points to no evidence that it could not revert to the former design in a similar way. It certainly has not provided any evidence that it tried to do so without success. *See Schedin v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F. Supp. 2d 1125, 1132 (D. Minn. 2011), *aff'd in part and rev'd in part by In re Levaquin Prods. Liability Litig.*, 700 F.3d 1161 (8th Cir. 2012) (holding that in order to satisfy *Wyeth*'s "clear evidence" standard with respect to a drug warning label, a "manufacturer likely must proffer evidence of the FDA's *rejection of an actual label change*").

Lycoming has not even argued that the proposed changes to its design would necessarily be "major"—but even if they would technically qualify as such, Lycoming has not carried its burden to show that the FAA would have

disapproved. For established manufacturers like Lycoming, many "major" changes are quite easy to make. Manufacturers with the appropriate delegations can make the changes themselves. *See Robinson v. Hartzell Propeller, Inc.*, 454 F.3d 163, 166 (3d Cir. 2006) ("Some manufacturers are able to grant themselves a type certificate."); FAA, Organization Designation Authorization Procedures, Order 8100.15B, at 2-4 (2013) (describing different Organization Designation Authorities, some of which can issue supplemental type certificates). And in many other cases, while the FAA may nominally be involved, the approval process will be perfunctory and success will be assured. Lycoming's own track record amending its O-320 type certificate dozens of times is proof of that. Separately, type certificate holders may submit changes that they feel contribute to product safety. *See* 14 C.F.R. § 21.99(b). Although, as a formal matter, such changes must be approved, there is little reason to suspect that the FAA would reject them.

Here, even if a design change would technically qualify as "major," Lycoming has not presented any evidence that if it had proposed such a change, the FAA would have rejected it. ECF No. 546 ¶32. The use of fuel injection and safety lock wire was, and remains, commonplace in aviation, and the evidence shows that safety wire works in MA-4SPA carburetors. Indeed, the FAA has not only approved the use of safety wire on the throttle body to bowl screws of MA-4SPA carburetors, but in fact required it in the prior airworthiness directive. *Id.* ¶27. It

strains credulity to think that the FAA would now prohibit a design feature that it previously deemed mandatory.[2]

[2] As the Third Circuit recognized, the "mere 'possibility' that the FAA would approve a hypothetical application for an alteration does not" necessarily defeat a preemption defense. *Sikkelee*, 822 F.3d at 704. The court based that statement on *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), which involved generic drug manufacturers who had no authority whatsoever to alter their own drug labels. Instead, the only recourse the generic manufacturers had was to ask the FDA to ask the brand-name manufacturers to alter their labels so that the generic manufacturers could alter theirs. The Court acknowledged that if the generic manufacturers had made such a request, "and if the FDA decided there was sufficient supporting information, and if the FDA undertook negotiations with the brand-name manufacturer, and if adequate label changes were decided on and implemented, then the Manufacturers would have started a Mouse Trap game that eventually led to a better label." *Id*. at 619. However, there was "no evidence of any generic drug manufacturer" ever attempting such a feat. *Id*. at 617.

On those facts, the Court decided that limiting impossibility preemption to situations in which that Mouse Trap game had been initiated would "render[] conflict pre-emption all but meaningless" because it is almost always possible to "imagine that a third party or the Federal Government *might* do something that makes it possible for a private party to accomplish under federal law what state law requires of it." *Id*. at 620. The Court acknowledged, however, that in other cases, "whether a private party can act sufficiently independently under federal law to do what state law requires may sometimes be difficult to determine." *Id*. at 623.

Lycoming's ability to alter its design is far greater than the generic manufacturers in *PLIVA*. Lycoming does not need any elaborate system of intermediaries to effect a design change; it has an open line of communication to the relevant officials and it has used those channels dozens of times before. Moreover, the alternative designs recommended here have already been approved, and the FAA itself has repeatedly expressed concern about the problems with the current design. In this case, then, even if Lycoming had to go through the formality of requesting an approval for a design change, there is far more than a "mere possibility" that approval would be granted. Lycoming's impossibility therefore defense must fail absent clear evidence that the FAA would say no.

Finally, Lycoming does not argue—much less show—that even if it had complied with its state-law duties and changed the design, Kelly would nevertheless have been bound by federal law to install a defective carburetor on Lycoming's engines. Such speculative factual causation arguments are always poor candidates for summary judgment, and especially so here because if Lycoming had never adopted its defective design, Kelly—which was merely trying to make parts to fit that design—would never have made the parts that it did. Similarly, if Lycoming had decided at some later point to revert to the safety wire design, deeming the change "minor," Kelly almost certainly would have done the same so that it could continue selling parts for Lycoming engines. *See* 14 C.F.R. § 21.319 (authorizing PMA holders to make minor design changes "using a method acceptable to the FAA"); FAA Order 8110.42D, at 2-15(a) (describing the minor change process); ECF No. 549 ¶42 (documenting several instances where Kelly has secured approval of minor changes to its PMA articles). Or, if Lycoming had changed the design after learning of the Malfunction or Defect Reports involving the carburetor or hearing from Precision about the ongoing problem, Kelly would have followed suit and changed its design too, consistent with its own obligation to ensure the safety of its articles on type certificated products. *See* 14 C.F.R. § 21.316(c). Indeed, if Lycoming had, at any point, notified the FAA and the public that its design was unsafe, Kelly almost certainly would have changed the

design or stopped manufacturing the relevant carburetor parts altogether. *Id*. That is because Lycoming, as the type certificate holder, is principally responsible for ensuring the safety of its product designs and resolving design-related service issues—and Kelly, as a part manufacturer, effectively rides piggyback on Lycoming's design choices. Indeed, when Kelly performed the overhaul in this case, it studiously complied with the documentation produced by Lycoming and by Precision. ECF No. 546 ¶39. Precision, in turn, had urged Lycoming, as the type certificate holder, to take a hard look at alternatives to lock tab washers. *Id*. ¶31. It stands to reason that if Lycoming had altered its design and documentation, then Precision would have done the same, and the manuals Kelly followed would have led Kelly to implement a different design. At a minimum, this causation question is factual and disputed.

Because Lycoming has not presented clear evidence that Kelly's PMA would make it impossible for Lycoming to comply with state law, its summary judgment motion must fail.

II. Kelly's PMA Does Not Otherwise Entitle Lycoming To Summary Judgment.

Part I of this brief dealt with the only argument Lycoming actually made—and then some. For the sake of completeness, we now address arguments that Lycoming did not make, but may attempt to raise in its reply brief. We do so not to open the door to these arguments, but instead only to give the Court comfort that it

need not consider them because in addition to being tardy, *see, e.g.*, *United States v. Medeiros*, 710 F. Supp. 106, 110 (M.D. Pa. 1989), they are meritless.

1. First, Lycoming may argue that its type certificate expressly approves every aspect of the type design, including the decision to use lock tab washers. Lycoming made this argument in supplemental briefing to the Third Circuit, arguing that each and every one of its drawings and specifications is part of its type certificate because the definition of a "type certificate" includes the "type design." But that simply cannot be true, because otherwise every single claim relating to a certificated design would be preempted. The Third Circuit rejected that outcome, refusing to hold "that the mere issuance of a type certificate exempts designers and manufacturers of defective airplanes from the bulk of liability for both individual and large-scale air catastrophes." *Sikkelee*, 822 F.3d at 696. Thus, when the Third Circuit and the FAA stated that "specifications expressly embodied" in a type certificate may give rise to conflict preemption, they clearly meant design features that the agency had actually considered and "affirmatively" blessed. *Id*. at 699, 702. At most, type certification constituted the FAA's determination that the design provisionally satisfied the fuel system regulation, 14 C.F.R. § 33.35, but that regulation does not say anything about how to attach throttle bodies to float bowls (or even whether to use carburetors). Because Lycoming has not presented any evidence that the FAA considered the lock tab washers and carburetor gasket

materials when certifying the O-320-D2C engine, it cannot satisfy the Third Circuit's conflict preemption test at the summary judgment stage.

2. Second, Lycoming may argue that because the FAA approved Kelly's designs for its PMA throttle body to bowl screws, lock tab washers, and gasket, it effectively delivered an express approval of Lycoming's decision to use those parts together to secure the throttle body to the bowl. This argument misconstrues the import of a PMA, which merely "substantiate[s] that the PMA article is at least equal to the original article approved under a type certificate" because the "[r]eplacement articles replicate the functionality and airworthiness of original articles from respective type certificates." FAA, Application for Parts Manufacturer Approval via Test and Computations or Identicality, Advisory Circular 21.303-4, at 11 (2014). Thus, when an applicant obtains a PMA by showing that its articles perform just as well as OEM parts, the applicant does not thereby prove anything about the quality of the type certificated design—it only proves that its articles do not themselves undermine that design.

Put differently, Kelly's PMA is essentially derivative of Lycoming's type certificate, and a far less robust approval at that. Thus, because the type certificate itself did not itself satisfy the Third Circuit's test, it follows that the PMA cannot do that work for Lycoming either. The fact that the PMA approvals are more granular than the type certificate (*i.e.*, that they are for a screw or a washer instead

of an engine) does not suggest that during the PMA process the FAA paid any attention to how the throttle body connects to the float bowl of an MA-4SPA carburetor on a Lycoming O-320-D2C engine and affirmatively approved that design choice. Instead, it merely reflects the happenstance that Kelly is not seeking approval to manufacture an entire engine, but instead only specific articles like washers and gaskets. There certainly is no basis to conclude that the PMA somehow approves the carburetor design as a whole. As Lycoming's exhibits make clear, the various PMA articles were approved piecemeal over time, not as a cohesive whole. *See* ECF No. 533-5 (approving gasket and washer); ECF No. 533-6 (approving minor change to gasket); ECF No. 533-7 (approving screw).

3. Third, Lycoming might argue that Sikkelee's claim poses an obstacle to Congress's purposes and objectives. That is incorrect. For purposes of this summary judgment motion, drawing all factual inferences in Sikkelee's favor, the Court must assume that Lycoming's design is defective, that Lycoming knew about the defect, and that the defect caused David Sikkelee's death. It must further assume that Lycoming failed adequately to warn consumers of the defect, and that it further failed to notify the FAA. Lycoming cannot make any credible argument that dismissing claims against manufacturers that knowingly maintain fatally defective designs is in any way consistent with Congress's purposes and objectives in enacting the Federal Aviation Act, *i.e.*, promoting aviation safety. Indeed, the

Act's liability-preserving features, including the savings clause and the exceptions to the GARA statute of repose (which is itself an exception to the general rule that general aviation manufacturers are liable for their design defects) conclusively prove otherwise.

Any obstacle preemption argument should meet the same fate as in *Wyeth*. There, the Supreme Court rejected the argument, explaining that state law acts "as a complementary form of drug regulation" that is necessary in light of the FDA's "limited resources" and manufacturers' "superior access to information about their drugs, especially in the postmarketing phase." 555 U.S. at 579. The Court elaborated that "[s]tate tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly" and also "serve a distinct compensatory function that may motivate injured persons to come forward with information." *Id*. "Failure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times." *Id*. These considerations apply with full force here.

III. Lycoming's Motion Is Outside The Scope Of The Third Circuit's Remand Order.

Independent of the merits, Lycoming's motion should be denied. With respect to conflict preemption, the Third Circuit remanded the case so that this Court could resolve the issues "discussed in supplemental briefing," *i.e.*, "whether the alleged

design defect at issue in this case is a design aspect that was expressly incorporated into the type certificate for the Textron Lycoming O-320-D2C engine and what significance that might have for conflict preemption." *Sikkelee,* 822 F.3d at 702.

Lycoming's argument, however, has nothing to do with the import of type certification because the PMA approval is not even arguably incorporated into the type certificate. Instead, Lycoming extrapolates from the Third Circuit's statements to make a new conflict preemption argument about PMAs. That argument is outside the scope of the remand, and not properly before the Court. Lycoming had the opportunity to raise any conflict preemption arguments based on PMA regulations during the years that summary judgment practice in this Court was open. It chose not to raise this argument then; it did not raise it in its supplemental brief to the Third Circuit (nor, for that matter, did anybody else); and the Third Circuit did not discuss it. Lycoming therefore cannot rely on the Third Circuit's opinion remanding the case to open the door to a new theory of conflict preemption that has nothing to do with type certification.

In any event, the disconnect between Lycoming's argument and the Third Circuit's holding also dooms it on the merits. Lycoming has no arguments based on type certification, and to the extent Lycoming is relying on the FAA for support, the agency's argument was likewise limited to the preemptive effect of type certification. It does not support Lycoming here.

CONCLUSION

Lycoming's motion for summary judgment should be denied.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of March, 2017, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send a notification of such filing to the all CM/ECF participants.

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CERTIFICATE OF COMPLIANCE

Pursuant to M.D. Pa. Local Rule 7.8(b), according to Microsoft Word's word count tool, the total words in this brief (not including table of contents, table of authorities, and signature blocks) totals 5,000 words.

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